New Zealand Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking Lagevrio?

Lagevrio contains the active ingredient molnupiravir. You are being given Lagevrio for the treatment of coronavirus disease 2019 (COVID-19). Lagevrio may help you to stay out of hospital and feel better. More information can be found in Section <u>1. Why am I taking Lagevrio?</u> in the full CMI.

2. What should I know before I take Lagevrio?

Tell your doctor or pharmacist about all of your medical conditions, including if you have any allergies, are pregnant or plan to become pregnant, are breastfeeding or plan to breast feed, have any serious illnesses, or are taking any medicines. Lagevrio is not recommended in pregnancy. Discuss the need for a pregnancy test with your doctor or pharmacist if you are of childbearing potential and sexually active. If you can become pregnant, you should use effective birth control while you are taking Lagevrio and for 4 days after the last dose of Lagevrio. If you are a male who is sexually active with a partner who has the potential to become pregnant, use a reliable method of contraception during treatment and for 3 months after the last dose of Lagevrio.

Breastfeeding is not recommended during treatment and for 4 days after the last dose of Lagevrio.

More information can be found in Section 2. What should I know before I take Lagevrio? in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

More information can be found in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take Lagevrio?

- Take Lagevrio exactly as your doctor tells you.
- Take 4 capsules of Lagevrio every 12 hours (for example, at 8 am and at 8 pm).
- Take Lagevrio for 5 days.
- Take Lagevrio with or without food.

More information can be found in Section <u>4. How do I take Lagevrio?</u> in the full CMI.

5. What should I know while taking Lagevrio?

Things you should do	• Tell the doctor, dentist, or pharmacist you visit that you are taking Lagevrio.
Things you should not do	 Do not stop taking this medicine without talking to your doctor first. Do not give Lagevrio to anyone else, even if they have the same condition as you.
Looking after your medicine	• Store Lagevrio in the original bottle in a cool dry place below 30°C, away from moisture, heat, and sunlight.

More information can be found in Section 5. What should I know while taking Lagevrio? in the full CMI.

6. Are there any side effects?

Any medicine may have unintended or undesirable effects, so called side effects. Allergic reactions can happen in people taking Lagevrio. The most common side effects of Lagevrio in adults are diarrhoea, nausea, and dizziness.

More information, including what to do if you have any side effects, can be found in Section <u>6. Are there any side effects?</u> in the full CMI.

Lagevrio[®] Capsules

Active ingredient(s): molnupiravir

New Zealand Consumer Medicine Information (CMI)

Please read this information carefully before you start using Lagevrio.

Remember that your doctor or pharmacist has prescribed or provided this medicine only for you. Never give it to anyone else.

This leaflet answers some common questions about Lagevrio. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Lagevrio against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

- <u>1.</u> <u>Why am I taking Lagevrio?</u>
- 2. What should I know before I take Lagevrio?
- 3. What if I am taking other medicines?
- 4. How do I take Lagevrio?
- 5. What should I know while taking Lagevrio?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking Lagevrio?

Lagevrio contains the active ingredient molnupiravir.

Lagevrio is an antiviral drug that works against the virus that causes coronavirus disease 2019 (COVID-19).

You are being given Lagevrio for the treatment of COVID-19. Lagevrio may help you to stay out of hospital and feel better.

Lagevrio is a medicine used to treat mild to moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and/or hospitalisation.

What is COVID-19?

- COVID-19 is caused by a virus called SARS CoV-2.
- You can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness, including breathing problems, can happen and may cause some of your other medical conditions to become worse.

Older people and people of all ages with severe, long lasting (chronic) medical conditions like heart disease, lung disease, obesity, and diabetes, for example seem to be at higher risk of being hospitalised for COVID-19.

What are the symptoms of COVID-19?

The symptoms of COVID-19 may include fever, cough, and shortness of breath.

2. What should I know before I take Lagevrio?

Tell your doctor or pharmacist about all of your medical conditions, including if you:

- have any allergies
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed
- have any serious illnesses

Pregnancy and Reproduction

- Animal studies with molnupiravir have shown harmful effects to the unborn animal.
- Lagevrio has not been studied in pregnancy in humans and it is not known if Lagevrio will harm your baby while you are pregnant.
- Lagevrio is not recommended in pregnancy. Discuss the need for a pregnancy test with your doctor or pharmacist if you are of childbearing potential and sexually active.
- If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice.
- If you can become pregnant, you should use effective birth control while you are taking Lagevrio and for 4 days after the last dose of Lagevrio.
- If you are a male who is sexually active with a partner who has the potential to become pregnant, use a reliable method of contraception during treatment and for 3 months after the last dose of Lagevrio.

Breastfeeding

- It is not known if Lagevrio gets into breast milk and will be passed to the baby.
- If you are breastfeeding or are planning to breastfeed, tell your doctor if before taking Lagevrio.
- Breastfeeding is not recommended during treatment and for 4 days after the last dose of Lagevrio.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

4. How do I take Lagevrio?

How to take Lagevrio

• Take Lagevrio exactly as your doctor or pharmacist tells you.

- Take 4 capsules of Lagevrio every 12 hours (for example, at 8 am and at 8pm).
- Take Lagevrio for 5 days. It is important that you complete the full 5 days of treatment with Lagevrio. Do not stop taking Lagevrio before you complete the full 5 days of treatment, even if you feel better
- Take Lagevrio with or without food.

If you forget to take Lagevrio

It is important that you do not miss or skip doses of this medicine.

What to do if you miss a dose:

- If it has been **less than 10 hours** since the missed dose, take it as soon as you remember.
- If it has been more than 10 hours since the missed dose, skip the missed dose and take your dose at the next scheduled time.

Do not double the dose of Lagevrio to make up for the missed dose. If you are not sure what to do, call your doctor or pharmacist.

If you take too much Lagevrio (Overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Lagevrio.

Do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Lagevrio?

Things you should do

Tell the doctor, dentist, or pharmacist you visit that you are taking Lagevrio and follow their advice.

Things you should not do

Do not stop taking this medicine without talking to your doctor or pharmacist first.

Do not give Lagevrio to anyone else, even if they have the same condition as you.

Looking after your medicine

Follow the instructions on the carton on how to store your medicine properly.

Store Lagevrio in the original bottle in a cool dry place below 30°C, away from heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Lagevrio.

Any medicine may have unintended or undesirable effects, so-called side effects.

Allergic Reactions:

Allergic reactions can happen in people taking Lagevrio, even after only 1 dose. Stop taking Lagevrio and call your healthcare provider right away if you get any of the following symptoms of an allergic reaction:

- hives
- rapid heartbeat
- trouble swallowing or breathing
- swelling of the mouth, lips, or face
- throat tightness
- hoarseness
- skin rash

The most common side effects of Lagevrio in adults are listed in the table below.

Common side effects	What to do
 diarrhoea nausea dizziness 	Speak to your doctor if you have any of these side effects and they worry you.

Other side effects may also occur rarely, and as with any prescription drug, some side effects may be serious. Ask your doctor or pharmacist for more information. Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is available with a doctor's prescription, or without a doctor's prescription after speaking with your pharmacist.

What Lagevrio contains

Active ingredient	molnupiravir 200 mg
(main ingredient)	
Other ingredients	croscarmellose sodium
(inactive ingredients)	hydroxypropyl cellulose
	magnesium stearate
	microcrystalline cellulose
	purified water
	Capsule shell:
	hypromellose

iron oxide red
titanium dioxide
White ink on the capsule:
butyl alcohol
dehydrated alcohol
isopropyl alcohol
potassium hydroxide
propylene glycol
purified water
shellac
strong ammonia solution
titanium dioxide

What Lagevrio looks like

Lagevrio is supplied in a bottle containing 40 capsules.

Lagevrio is available as a Swedish Orange opaque capsule with corporate logo and "82" printed with white ink for oral administration.

Who distributes Lagevrio

Lagevrio is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited PO Box 99851 Newmarket Auckland 1149 New Zealand Tel: 0800 500 673

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